

## Pre-Quarterly Results Communication Q4 2015

### New information for Q4 2015

#### Foreign exchange

Average rates for the year 31<sup>st</sup> December 2015 were \$1.53/£, €1.37/£ and Yen 185/£. On the basis of these rates, it is expected that the impact of foreign exchange on FY 2015 sales will be around -2%.

Average rates for the quarter ended 31<sup>st</sup> December 2015 were \$1.53/£, €1.37/£ and Yen 185/£. On the basis of these rates, it is expected that the impact of foreign exchange on Q4 2015 sales will be around -3%.

As a result of the mix of currency movements relative to the mix of costs, we expect that the negative impact of foreign exchange on full year 2015 sterling core EPS will be greater than the negative impact on sales. Over the first nine months of 2015, the impact of currencies on core EPS was -5% compared with the -1% impact on sales.

We also expect that the negative impact of foreign exchange on Q4 2015 sterling core EPS will likely be greater than the negative impact on sales.

Average rates Cumulative - YTD	3M 2014	6M 2014	9M 2014	12M 2014	3M 2015	6M 2015	9M 2015	12M 2015
<b>Key Currencies</b>								
US\$	1.66	1.67	1.67	1.65	1.52	1.53	1.53	1.53
€	1.21	1.22	1.23	1.24	1.34	1.36	1.37	1.37
Yen	171	172	173	175	182	184	185	185
<b>Other Currencies</b>								
Australian Dollar	1.85	1.83	1.83	1.83	1.94	1.96	2.02	2.03
Brazilian Real	3.89	3.84	3.84	3.88	4.33	4.53	4.85	5.09
Canadian Dollar	1.83	1.83	1.82	1.82	1.88	1.89	1.93	1.95
Chinese Yuan	10.2	10.3	10.3	10.2	9.49	9.53	9.58	9.60
Indian Rupee	102.0	102.0	102.0	101.0	94.9	96.4	97.5	98.0
Russian Rouble	57.8	58.3	59.4	63.9	94.7	89.4	92.1	94.4
<b>FX impact on turnover</b>								
	-8%	-9%	-8%	-7%	-1%	-1%	-1%	-2%E
<b>FX impact on CORE EPS</b>								
	-22%	-17%	-12%	-11%	-2%	-6%	-5%	n/a

Average rates Quarterly	Q1 2014	Q2 2014	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015	Q4 2015
<b>Key currencies</b>								
US\$	1.66	1.68	1.67	1.59	1.52	1.54	1.53	1.53
€	1.21	1.23	1.25	1.27	1.34	1.38	1.39	1.37
Yen	171	173	175	181	182	186	187	185
<b>Other Currencies</b>								
Australian Dollar	1.85	1.81	1.83	1.83	1.94	1.98	2.14	2.06
Brazilian Real	3.89	3.79	3.84	4.00	4.33	4.73	5.49	5.81
Canadian Dollar	1.83	1.83	1.80	1.82	1.88	1.90	2.01	2.01
Chinese Yuan	10.2	10.4	10.2	9.90	9.49	9.57	9.68	9.66
Indian Rupee	102.0	102.0	102.0	98.0	94.9	97.9	99.7	99.5
Russian Rouble	57.8	58.8	61.6	77.4	94.7	84.1	97.5	101.3
<b>FX impact on turnover</b>	<b>-8%</b>	<b>-9%</b>	<b>-7%</b>	<b>-3%</b>	<b>-1%</b>	<b>-1%</b>	<b>-2%</b>	<b>-3%E</b>
<b>FX impact on CORE EPS</b>	<b>-22%</b>	<b>-13%</b>	<b>-5%</b>	<b>-5%</b>	<b>-2%</b>	<b>-9%</b>	<b>-5%</b>	<b>n/a</b>

The Q4 2015 period-end rates were \$1.47/£, €1.36/£ and Yen 177/£.

Period end rates	Mar 2014	Jun 2014	Sep 2014	Dec 2014	Mar 2015	Jun 2015	Sep 2015	Dec 2015
<b>Key Currencies</b>								
US\$	1.67	1.71	1.62	1.56	1.48	1.57	1.51	1.47
€	1.21	1.25	1.28	1.29	1.38	1.41	1.36	1.36
Yen	172	173	178	187	178	192	181	177

### Exchange Gains or (Losses)

Sharp movements and volatility in currencies during a quarter can result in Exchange Gains or Losses (EGOLs) which are recorded in SG&A. During Q4 2015 there was continued volatility in a number of currencies relative to Sterling.

EGOLs as reported (£m)	Q1	Q2	Q3	Q4	Full Year
2013	82	(46)	(49)	(14)	(27)
2014	(20)	(27)	10	(19)	(56)
2015	(6)	(61)	0		

### Ready reckoner

At the GSK Investor Event on 6 May 2015, the following ready reckoner was provided on slide 77 to help estimate the expected impact of foreign exchange movements on core EPS\*:

Currency	Impact on 2015 Full Year Core EPS
US Dollar	10 cents movement in average exchange rate for full year impacts EPS by approximately +/-3%
Euro	10 cents movement in average exchange rate for full year impacts EPS by approximately +/-2%
Japanese Yen	10 Yen movement in average exchange rate for full year impacts EPS by approximately +/-1%

\*Please note that the ready reckoner does not include the impact of inter-company Exchange Gains or Losses

The slide also included 2014 currency sales exposure for legacy GSK:

Currency	2014 Currency sales exposure
US Dollar	32%
Euro	20%
Japanese Yen	7%
Other*	41%

\*The other currencies that each represent more than 1% of Group sales are: Australian Dollar, Brazilian Real, Canadian Dollar, Chinese Yuan, Indian Rupee. In total they accounted for 13% of Group revenues in 2014

### Currency impact 2016

We will give you our view on the impact of currencies in 2016 in our fourth quarter 2015 press release on 3 February 2016.

### Basic weighted average number of shares (WANS)

The basic weighted number of shares in issue during 2015 was 4,831m compared with 4,808m in 2014 (an increase of 0.5%).

The basic weighted number of shares in issue during Q4 2015 was 4,838m compared with 4,809m in Q4 2014 (an increase of 0.6%).

In millions	Q1 2014	Q2 2014	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015	Q4 2015
<b>WANS: Quarter</b>	4,802	4,812	4,807	4,809	4,820	4,832	4,835	4,838
<b>WANS: Cumulative - Year to date</b>	4,802	4,807	4,807	4,808	4,820	4,826	4,829	4,831
Period end shares *	4,815	4,805	4,808	4,811	4,830	4,834	4,836	4,840

\*excludes Treasury shares and shares held by ESOP Trusts

### Dividend

In the Q3 2015 press release we made the following comment on returns to shareholders:

*“GSK expects to pay an annual ordinary dividend of 80p for each of the next three years (2015-2017). GSK also plans to return approximately £1 billion (20p per share) to shareholders via a special dividend to be declared on 3 February 2016.*

*Any future returns to shareholders of surplus capital will be subject to the Group’s strategic progress, visibility on the put options associated with ViiV Healthcare and the Consumer Healthcare joint venture and other capital requirements.”*

Dividend per share (p)	Q1	Q2	Q3	Q4	Full Year
2013	18	18	19	23	78
2014	19	19	19	23	80
2015 – ordinary dividend	19	19	19		80*
2015 – special dividend	-	-	-	20*	20*

\*The actual dividend amount is determined by the Board of Directors.

### Factors impacting recent quarterly comparisons

As usual there were a number of events in 2015 and during 2014 which impact the year on year comparison for Q4 2015 and full year 2015. This includes the following noteworthy items which you may wish to consider in your modelling.

**Please note that the items listed below are not intended to be a complete list of all items that may impact the comparisons for Q4 2015 versus Q4 2014.**

For further comments, please refer to quarterly press releases and webcast/analyst presentation transcripts.

#### **General comments on Q4 2015**

On the Q3 2015 results analyst/investor call on 28 October 2015, Simon Dingemans (Chief Financial Officer) made the following comments:

*“In the short term, we have always expected that the transition of the business post-Novartis would create some quarterly volatility in 2015, given some of the uncertainty around the timing of the delivery of transaction benefits, and some of the material quarter-to-quarter drag factors. Q4 will be no exception, with the biggest quarter last year for Oncology sales dropping out, along with Avodart going generic in the US at the start of Q4 as well as the usual lumpy comparisons for vaccine sales, depending on the timing of tenders. We also expect continued growth in the minority interest, given the increasing contributions from HIV sales and the Consumer joint venture, and a much higher tax rate than in Q4 last year. We still expect the effective tax rate for 2015 as a whole to be around 20%.”*

#### **Respiratory**

On the Q3 2015 results analyst/investor call on 28 October 2015, Simon Dingemans (Chief Financial Officer) made the following comments:

*“US Pharma sales were down 10% proforma, primarily driven by Advair which was down 18%. It is down 19% year-to-date as we absorb the price reductions we agreed last year, but also as we transition our portfolio to the new products.*

*Our new products, Breo and Anoro, are building some momentum and together had sales of £41 million, more than double Q3 last year. We have completed the vast majority of the contracting with Managed Care for next year, and as a result we expect the formulary coverage in 2016 for all of our respiratory products to be as good as, or better than, in 2015”*

*“In Europe, Pharma sales were down 7% pro forma, Respiratory down 13% and Seretide down 23%. This reflects a step-up that we have seen in competitive action in the quarter with a number of new generics being launched and competitive tender activity particularly impacting volume share. Pricing pressures will continue and, as we shift our own Respiratory business to the new products, Seretide is likely to decline further. In the year to date, Seretide is down 17%.*

Offsetting that we are seeing encouraging signs in the roll-out of the new products. For example, in Italy Relvar volume share gains have almost completely eroded Seretide's share losses, and both Relvar and Anoro have now been launched in the vast majority of European markets. In Q3 total sales for Relvar and Anoro in Europe were £25 million, offsetting around a third of the Seretide sales decline."

"Within Respiratory, Emerging Market sales of Seretide were down 15% with additional generic competition, price reductions in a number of reimbursed markets flowing through in the quarter, and the impact of our own shift in new products in a number of early launch markets such as Brazil. Increased generic activity is likely to create some continuing quarter to quarter volatility going forward for EM's Respiratory."

Seretide/Advair (£m)	Q1 2014	Q2 2014	Q3 2014	Q4 2014	FY 2014	Q1 2015	Q2 2015	Q3 2015
US	455	528	441	548	1,972	392	484	397
Europe	352	348	314	316	1,330	291	267	224
Emerging Markets	97	98	94	111	400	n/a	n/a	n/a
International	232	219	221	255	927	215	209	173
<b>Total</b>	<b>1,039</b>	<b>1,095</b>	<b>976</b>	<b>1,119</b>	<b>4,229</b>	<b>898</b>	<b>960</b>	<b>794</b>
<b>CER growth</b>								
US	-30%	-19%	-25%	-27%	-25%	-21%	-17%	-18%
Europe	-3%	-4%	-5%	-9%	-5%	-11%	-16%	-23%
Emerging Markets	+4%	-4%	+20%	-2%	+3%	n/a	n/a	n/a
International	n/a	n/a	n/a	n/a	n/a	-4%	+0%	-13%
<b>Total</b>	<b>-15%</b>	<b>-12%</b>	<b>-13%</b>	<b>-18%</b>	<b>-15%</b>	<b>-14%</b>	<b>-13%</b>	<b>-19%</b>

## HIV

On the Q2 2015 results analyst/investor call on 29 July 2015, Simon Dingemans made the following comments with respect to the HIV margin:

"In terms of overall trend clearly the quarter is above trend at 74%. That's really reflecting the leverage from the top-line growth and the SG&A behind that.

What we haven't got in the P&L at the moment is some of the R&D that we expect to start putting back into the P&L as the pipeline progresses. Overall, and I know we've had a number of questions on this, if you think of a trend of around 70%, you are probably in the right place and clearly the margin quarter to quarter is going to move around that, depending on where we are in the development of current and future products."

HIV (£m)	Q1 2014	Q2 2014	Q3 2014	Q4 2014	FY 2014	Q1 2015	Q2 2015	Q3 2015
Turnover	311	352	373	462	1,498	446	559	622
Operating profit	204	225	246	302	977	318	413	466
Operating margin	65.6%	63.9%	66.0%	65.4%	65.2%	71.3%	73.9%	74.9%

## Vaccines

Sales of vaccines are vulnerable to volatility on a quarterly basis – particularly in emerging markets. Since quarterly sales can be very lumpy due in part to the impact of large tenders as well as competitor outages we highlight below the results for the Vaccines business in 2014 and 9M 2015:

GSK Vaccines (£m)	Q1 2014	Q2 2014	Q3 2014	Q4 2014	FY 2014	FY 2014 12 month Pro Forma	Q1 2015	Q2 2015	Q3 2015
US	172	192	337	229	930	n/a	217	240	526
Europe	240	239	259	240	978	n/a	224	274	308
Emerging Markets	190	283	274	309	1,056	n/a	n/a	n/a	n/a
International	246	335	326	377	1,284	n/a	258	300	347
<b>Total turnover</b>	<b>658</b>	<b>766</b>	<b>922</b>	<b>846</b>	<b>3,192</b>	<b>£3.7bn</b>	<b>699</b>	<b>814</b>	<b>1,181</b>
Operating profit						£0.8bn	161	177	464
Operating margin						22.4%	23.0%	21.7%	39.3%
<b>CER growth</b>									
US – reported	+25%	-2%	-3%	-9%	+0%		+14%	+13%	+42%
<b>US – PF*</b>							<b>+11%</b>	<b>-5%</b>	<b>+22%</b>
Europe – reported	+3%	-5%	+0%	-7%	-2%		+4%	+27%	+31%
<b>Europe – PF*</b>							<b>-3%</b>	<b>+12%</b>	<b>+14%</b>
Emerging Markets	-8%	+26%	+13%	-16%	+1%		n/a	n/a	n/a
International – rep'd	n/a	n/a	n/a	n/a	n/a		+13%	-2%	+22%
<b>International – PF*</b>							<b>+3%</b>	<b>-16%</b>	<b>+3%</b>
<b>Turnover – reported</b>	<b>+3%</b>	<b>+5%</b>	<b>+0%</b>	<b>-9%</b>	<b>-1%</b>		<b>+10%</b>	<b>+11%</b>	<b>+32%</b>
<b>Turnover – PF*</b>							<b>+3%</b>	<b>-5%</b>	<b>+13%</b>

\*PF (pro forma) growth rates for vaccines for Q1, Q2 and Q3 2015 were calculated by comparing reported turnover for the quarter with the corresponding quarter of 2014 adjusted to include the equivalent one month's sales of the former Novartis vaccines business in Q1 and three months of the former Novartis vaccines business in Q2 and Q3.

On the Q3 2015 results analyst/investor call on 28 October 2015, Simon Dingemans made the following comments with regard to the performance in Q3 2015:

*“Turning to Vaccines, overall a strong quarter: 13% growth on a pro forma basis. US Vaccines up 22% pro forma, with flu vaccine sales up 59%, benefiting from earlier supply in the quarter than last year, more doses and the switch to 100% quadrivalent this year. For the quarter, we sold roughly 22 million doses versus last year's 15 million doses. Our new meningitis products, Menveo and Bexsero, also delivered strong growth with total sales up 34%. In Europe, Vaccine sales grew 14% pro forma mainly driven by our meningitis portfolio led by Bexsero sales of £28 million and Menveo with £14 million. Bexsero has particularly benefited from inclusion in the UK immunisation programme but also from good private market sales in a number of other major countries.*

*Boostrix is up 30% with strong growth in Germany. Hepatitis sales were down 15% mainly because of the supply constraints that we have previously talked about.*

*In International, Vaccine sales were up 3% pro forma against a tough comparator. Strong growth for Synflorix was up 19%, mostly offset by lower sales of Boostrix, down nearly 50% with significant competition arriving in the tender space and a number of capacity constraints, as well as hepatitis sales which were also down, reflecting the same constraints.*

*We continue to make investments in the supply chain to improve overall reliability and expand capacity for the future, but it will take into 2017 before the programme is fully complete.”*

With regard to Q4 2015, in addition to pointing out that progress in our supply chains, “allowed us to move early on the important seasonal businesses of flu vaccines [in Q3],” Simon Dingemans noted the potential for “lumpy comparisons for vaccine sales, depending on the timing of tenders.”

### Consumer Healthcare

Here are the quarterly results for the Consumer Healthcare Business in 2014 and 9M 2015:

GSK Consumer Healthcare (£m)	Q1 2014	Q2 2014	Q3 2014	Q4 2014	FY 2014	FY 2014 12 month Pro Forma	Q1 2015	Q2 2015	Q3 2015
Turnover	1,127	1,022	1,071	1,116	4,336	£6.1bn	1,381	1,509	1,576
Reported growth - CER	+0%	-4%	-3%	+2%	-1%		+24%	+51%	+55%
Pro forma* growth - CER	n/a	n/a	n/a	n/a	n/a		+8%	+6%	+7%
Operating profit						£0.7bn	182	108	210
Operating margin						11.0%	13.2%	7.2%	13.3%

*\*pro forma growth rates for Consumer Healthcare for Q1, Q2 and Q3 2015 were calculated by comparing reported turnover for the quarter with the corresponding quarter of 2014 adjusted to include the equivalent one month’s sales of the former Novartis Consumer Healthcare business in Q1 and three months of the former Novartis Consumer Healthcare business in Q2 and Q3.*

On the Q3 2015 results analyst/investor call on 28 October 2015, Simon Dingemans made the following comments:

*“Consumer Healthcare is up 7% pro forma, with estimated consumption data for the portfolio in line with this rate and several points ahead of market growth. In the US, the business continued to benefit from Flonase OTC sales following its strong launch, which particularly benefited Q1. The International business delivered a more encouraging performance in the quarter, up 6% with strong performances from India and a return to growth in Russia. Destocking has had less of an impact than in Q2 but the higher channel inventories of the acquired businesses in a few markets, particularly China and the Middle East will continue to be a drag on growth through into the first quarter of next year, particularly in Wellness.”*

On the same call in response to a question, Andrew Witty (Chief Executive Officer) made the following comments:

*“Now, as you think about SG&A going forward, there is going to be volatility quarter-to-quarter. I will give you a very specific example. Q3 was pretty light for Consumer, but Q4 is going to be pretty heavy for Consumer because of the cough and cold season and the shifts around, and as you know, post the transaction we have a much bigger cough and cold portfolio than we had before the transaction, so you are going to see a few movements like that.”*

### Corporate and other unallocated turnover

In the Q3 2015 press release we made the following comments on corporate and other unallocated turnover :

*“The Corporate and unallocated turnover of £74 million represented sales of several Vaccines and Consumer Healthcare products, which were being held for sale in a number of markets. GSK was required to dispose of these products in specific markets in order to meet the requirements of the anti-trust approvals for the Novartis transaction. The disposals were completed in Q3 2015”*

Corporate and unallocated turnover as reported (£m)	Q1	Q2	Q3	Q4	Full Year
2015	19	25	30		

### Operating and financial performance

#### Operating performance

On the Q3 2015 results analyst/investor call on 28 October 2015, Simon Dingemans made the following comments:

*“Year-to-date, the core margin is down 320 basis points, 270 of this due to the Novartis transaction, and I continue to expect the impact of the transaction for the full year to be in the 200-300 basis point range. Including the year-to-year comparators which we have covered a couple times, we still expect the overall decline in the reported core margin for the full year to be in the order of 500 basis points.”*

CORE operating margin	Q1	Q2	Q3	Q4	Full Year
2014	27.3%	25.3%	33.4%*	28.6%	28.7%*
2015	23.2%	22.9%	28.0%		
Change year-on-year	-410 bps	-240 bps	-540 bps		Around 500bps decline

\*Q3 2014 included a structural variance of £219m which benefited the Q3 2014 operating margin by 390bps and the full year 2014 operating margin by 100 bps



### Year on year cost savings (per Investor event presentation)

Restructuring and structural savings (£bn)*	2014	2015	2016	2017
Restructuring savings (cumulative)	0.6	1.4	2.1	2.9
Structural savings	0.2	-	-	-
Total savings	0.8	1.4	2.1	2.9
Incremental savings		+0.6	+0.7	+0.8

\* Expected phasing of annual savings. All expectations and targets regarding future performance should be read together with the “2015-2020 Outlook” and “Assumptions and cautionary statement regarding forward-looking statements” sections of the Q1 Results Announcements dated 6 May 2015.

In the Q3 2015 press release we made the following comments on restructuring:

*“Major restructuring charges accrued in the nine months were £1,118 million (2014: £293 million) and reflected the acceleration of a number of restructuring projects following completion of the Novartis transaction. Cash payments made in the 9 months to 30 September 2015 were £867 million (2014: £359 million). The programme has delivered £0.7 billion of incremental benefit in the quarters to 30 September 2015 compared with the same period in 2014.*

*Charges for the combined restructuring and integration programme to date are £2.0 billion. The total cash charges of the combined programme are expected to be approximately £3.65 billion and the non-cash charges up to £1.35 billion. By the end of the third quarter, the programme had delivered approximately £1.3 billion of annual savings and remains on track to deliver £3 billion of annual savings in total. The programme is expected to be largely complete by 2017.”*

In the Q3 2015 results analyst/investor call on 28 October 2015, Simon Dingemans made the following comments on cost savings:

*“Overall, as we came out of the third quarter, we were at an annual run rate of around £1.3 billion in total for the various programmes that we have now aggregated. We were targeting £1.4 billion for the end of the year and so there is a good opportunity to do a little better than we had planned for the year as a whole. Let’s see how the fourth quarter goes: I think it is a little premature to be changing the total targets that we have for the overall programme of £3 billion by 2017.”*

### Financial performance

#### Associates and joint ventures

In the Q1 2015 results video on 6 May 2015, Simon Dingemans made the following comments relating to associates:

*“Profit from associates was £7m vs £1m in Q1 last year. But now that we are no longer accounting for Aspen as an equity affiliate, following the sale of half of our shares for around half a billion pounds in March, we expect this line to be immaterial for the rest of the year.”*

CORE associates and joint ventures (£m)	Q1	Q2	Q3	Q4	Full Year
2014	1	8	10	11	30
2015	7	(2)	(2)		

### Taxation

In the Q3 2015 press release we made the following comments on taxation:

*“The core tax rate for the full year is also expected to be around 20%”*

In the Q3 2015 results analyst/investor call on 28 October 2015, Simon Dingemans pointed out that we expect “a much higher tax rate [in Q4 2015] than in Q4 last year.”

CORE Tax rate	Q1	Q2	Q3	Q4	Full Year
2014	22.0%	22.0%	20.0%	15.3%	19.6%
2015	20.0%	20.0%	20.0%		Around 20%

### Profit/(loss) attributable to non-controlling interests (minority interests)

In the Q3 2015 press release we made the following comments

*“The allocation of earnings to non-controlling interests amounted to £141 million (Q3 2014: £47 million), the increase reflecting the Consumer Healthcare non-controlling interest allocation together with an increase in the allocation of ViiV Healthcare profits.”*

On the Q3 2015 results investor/analyst call on 28 October 2015, Simon Dingemans made the following comments relating to the Q4 2015 outlook for minority interests:

*“We also expect continued growth in the minority interest, given the increasing contributions from HIV sales and the Consumer joint venture.”*

CORE profit/(loss) attributable to non-controlling interests (£m)	Q1	Q2	Q3	Q4	Full Year
2014	(62)	(61)	(47)	(52)	(222)
2015	(91)	(99)	(141)		

## Historic London Stock Exchange Announcements (LSE announcements) and press releases

### Acquisitions and Divestments

#### **GSK completes divestment of rights to ofatumumab for auto-immune indications to Novartis**

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced the completion of its transaction to divest its rights to ofatumumab for auto-immune indications to Novartis Pharma AG (“Novartis Pharma”), a subsidiary of Novartis AG, following regulatory approval.

The consideration payable by Novartis Pharma to GSK may reach up to \$1,034 million and comprises a series of milestone payments as follows:

- \$300 million paid at closing
- \$200 million payable subject to the start of a phase III study in relapsing remitting multiple sclerosis by Novartis
- further contingent payments of up to \$534 million payable on the achievement of certain other development milestones

Novartis Pharma will also pay royalties of up to 12 per cent to GSK on any future net sales of ofatumumab in auto-immune indications.

Income generated from the divestment will be treated as non-core in line with the accounting policies outlined in the third quarter financial results announcement of 28 October 2015.

[\(LSE announcement 21 December 2015\)](#)

#### **GSK’s global HIV business ViiV Healthcare to acquire Bristol-Myers Squibb’s R&D HIV assets**

- Two transactions further strengthen HIV pipeline and outlook

GlaxoSmithKline plc (LSE: GSK) today announced that its global HIV business, ViiV Healthcare, has reached two separate agreements with Bristol-Myers Squibb, to acquire its late-stage HIV R&D assets; and to acquire Bristol-Myers Squibb’s portfolio of preclinical and discovery stage HIV research assets.

Under the terms agreed in the two transactions, ViiV Healthcare will acquire:

- Late stage assets, including fostemsavir (BMS-663068), an attachment inhibitor, currently in phase III development for heavily treatment experienced patients. Fostemsavir has received a Breakthrough Therapy Designation from the FDA and is expected to be filed for regulatory approval in 2018. The second late stage asset is a maturation inhibitor (BMS-955176), currently in phase IIb development for both treatment-naive and treatment experienced patients. A back-up maturation inhibitor candidate (BMS-986173) is also included in the purchase.
- Assets in preclinical and discovery phases of development including a novel biologic (BMS-986197) with a triple mechanism of action, a further maturation inhibitor, an allosteric integrase inhibitor and a capsid inhibitor. A number of Bristol-Myers Squibb drug discovery employees will also be offered the opportunity to transfer to ViiV Healthcare.

[\(LSE announcement 18 December 2015\)](#)

**Amgen reacquires all product rights to Prolia® (denosumab), XGEVA® (denosumab) and Vectibix® (panitumumab) from GSK in 48 countries**

<http://wwwext.amgen.com/media/news-releases/2015/12/amgen-reacquires-all-product-rights-to-prolia-denosumab-xgeva-denosumab-and-vectibix-panitumumab-from-gsk-in-48-countries/>

**(Amgen press release 14 December 2015)**

**GSK completes partial sale of Aspen Pharmacare Holdings Ltd shares**

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**(LSE announcement 13 March 2015)**

<http://otp.investis.com/clients/uk/GlaxoSmithKline2/rns/regulatory-ystor.aspx?cid=410&newsid=497569>

**Novartis transaction announcements**

In the Q3 2015 press release we made the following comment on business acquisitions and disposals.

*“On 28 August 2015, GSK completed the disposal of various Consumer Healthcare products in a number of markets for cash consideration of £145 million. On 30 September 2015, GSK also completed the disposal of two meningitis vaccines in a number of markets for cash consideration of £55 million. Both of these disposals were required to meet anti-trust approvals for the Novartis transaction “*

This links below contain the respective press releases from Perrigo and Pfizer relating to these divestments.

[http://www.pfizer.com/news/press-release/press-release-detail/pfizer\\_completes\\_acquisition\\_of\\_nimenrix\\_and\\_mencevax\\_from\\_glaxosmithkline](http://www.pfizer.com/news/press-release/press-release-detail/pfizer_completes_acquisition_of_nimenrix_and_mencevax_from_glaxosmithkline)

<http://perrigo.investorroom.com/2015-08-28-Perrigo-Completes-Acquisition-of-Leading-Portfolio-of-OTC-Brands-from-GSK>

### [News flow on key assets during the quarter and to date](#)

Since the beginning of Q4 we have issued a number of LSE announcements and press releases, each of which can be accessed using the following link:

<http://www.gsk.com/en-gb/media/press-releases/>

#### **ViiV Healthcare to progress collaboration with Janssen to develop the first long-acting, two drug injectable regimen for treatment of HIV-1 infection**

ViiV Healthcare, a global specialist HIV company with GSK, Pfizer Inc. and Shionogi Limited as shareholders, today formalised its collaboration with Janssen Sciences Ireland UC (Janssen) for the phase III investigation and commercialisation of the long-acting, injectable formulations of cabotegravir (ViiV Healthcare) and rilpivirine (Janssen) for the treatment of HIV-1 infection. The long-acting formulations of cabotegravir (CAB LA) and rilpivirine (RPV LA) are being investigated as an injectable maintenance treatment for patients who have achieved viral suppression.

[\(ViiV Healthcare press release 07 January 2016\)](#)

#### **GSK receives positive top-line results from sirukumab phase III programme supporting regulatory filings for rheumatoid arthritis in 2016.**

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced it has received positive top-line results from the phase III programme investigating sirukumab, a human anti-interleukin (IL)-6 monoclonal antibody for the treatment of patients with moderately to severely active rheumatoid arthritis (RA), in development as part of a collaboration with Janssen Biologics (Ireland) [Janssen].

[\(LSE announcement 16 December 2015\)](#)

#### **GSK receives European marketing authorisation for Nucala® (mepolizumab) in 31 countries**

First anti-IL-5 treatment for patients with severe refractory eosinophilic asthma in the EU

GlaxoSmithKline (LSE/NYSE: GSK) today announced that the European Commission has granted marketing authorisation for Nucala® (mepolizumab) as an add-on treatment for severe refractory eosinophilic asthma in adult patients. As a result Nucala is now approved for use in the 31 European countries covered by the European Medicines Agency (EMA). [\(Press release 02 December 2015\)](#)

#### **GSK announces start of phase III study of sirukumab in Giant Cell Arteritis**

GSK today announced that dosing has commenced in a phase III study evaluating sirukumab, a human anti-interleukin (IL)-6 monoclonal antibody, for the treatment of patients with giant cell arteritis (GCA). [\(Press release 25 November 2015\)](#)

#### **GSK receives European marketing authorisation to expand indication for Volibris® in treatment of pulmonary arterial hypertension**

GSK today announced that the European Commission has approved a variation to expand the current therapeutic indication for Volibris® (ambrisentan) to include its use in combination treatment for patients with pulmonary arterial hypertension (PAH). Volibris is indicated for treatment of PAH in adult patients of WHO Functional Class (FC) II to III, including use in combination treatment. [\(Press release 24 November 2015\)](#)

### **GSK announces positive results from phase III BLISS-SC study of Benlysta® (belimumab) administered subcutaneously in patients with systemic lupus erythematosus**

GSK today announced results from the BLISS-SC Phase III pivotal study in patients with active, autoantibody-positive systemic lupus erythematosus (SLE). These results, which are being presented at the American College of Rheumatology/Association for Rheumatology Health Professionals Annual Meeting, showed that Benlysta® (belimumab) 200mg administered weekly via subcutaneous injection plus standard of care (SoC), showed significantly greater reductions in disease activity compared to placebo plus SoC. ([Press release 07 November 2015](#))

### **GSK's Nucala® (mepolizumab) receives approval from US FDA**

- First anti-IL5 treatment for adults and adolescents with severe asthma with an eosinophilic phenotype

GlaxoSmithKline plc (LSE/NYSE: GSK) today received approval from the US Food and Drug Administration (FDA) for its Biologics License Application (BLA) for Nucala® (mepolizumab) as an add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Nucala is not approved for the treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus. ([LSE announcement 04 November 2015](#))

### **ViiV Healthcare announces positive headline results from a study of two drug injectable regimen for HIV maintenance therapy**

ViiV Healthcare, a global specialist HIV company with GSK, Pfizer Inc. and Shionogi Limited as shareholders, today announced that the Phase IIb study LATTE 2 (NCT02120352) met its primary endpoint at 32 weeks. These results show that the investigational, long acting, injectable formulations of cabotegravir (ViiV Healthcare) and rilpivirine (Janssen) were comparable in maintaining viral suppression rates to a three drug oral regimen of investigational cabotegravir and two nucleoside reverse transcriptase inhibitors (NRTIs). The 32 week results of LATTE 2 will be presented at a forthcoming scientific conference. ViiV Healthcare and Janssen Sciences Ireland UC (Janssen) are collaborating to conduct LATTE 2. ([LSE announcement 03 November 2015](#))

### **GSK and Merck to study immunotherapy combination as potential cancer treatment**

- Phase I first-in-human study to evaluate GSK's OX40 agonist GSK3174998 as monotherapy and in combination with Merck's anti-PD-1 therapy, Keytruda® (pembrolizumab)

GSK and Merck, known as MSD outside the US and Canada, today announced the initiation of a phase I clinical trial designed to evaluate GSK's investigational immunotherapy GSK3174998 as monotherapy and in combination with Merck's anti-PD-1 therapy, Keytruda® (pembrolizumab) in patients with locally advanced, recurrent or metastatic solid tumour(s) that have progressed after standard treatment.

GSK3174998 is a humanised IgG1 anti-OX40 monoclonal antibody that was identified through a collaboration with MD Anderson Cancer Center. OX40 is a tumour necrosis factor receptor expressed on the surface of activated CD4+ and CD8+ T cells. OX40 agonism results in stimulation of both immune effector and memory functions, while also attenuating the immunosuppressive regulatory T cells that are sometimes found in tumours. GSK3174998 is one of a number of early stage assets in GSK's oncology pipeline focused on fighting the fundamental drivers of cancer. Keytruda is a humanised monoclonal antibody that works by increasing the ability of the body's

immune system to help detect and fight tumour cells. Keytruda blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, and may affect both tumour cells and healthy cells.

[\(Press release 03 November 2015\)](#)

#### **GSK profiles innovative R&D portfolio to investors**

- 40 potential new medicines and vaccines offer significant opportunity to drive long-term performance and deliver new benefits to patients and consumers

At a presentation to investors in New York today, GSK described a deep portfolio of innovation, focussed across six core areas of scientific research and development: HIV & Infectious diseases, Oncology, Immuno-Inflammation, Vaccines, Respiratory and Rare Diseases. Around 40 new potential medicines and vaccines were profiled, supporting the Group's outlook for growth in the period 2016-2020 and the significant opportunity the Group has to create value beyond 2020.

The portfolio represents some of the latest scientific achievements from GSK's R&D organisation and its more than 1,500 company and academic collaborations. The company believes approximately 80% of the medicines and vaccines presented have the potential to be "first-in-class" with novel mechanisms of action. As a result, many of these potential medicines and vaccines may offer benefits beyond current standards of care and, in some cases, could radically transform how patients are treated. [\(LSE announcement 03 November 2015\)](#)

#### **GSK Exercises Option on Oxford BioMedica's LentiVector® Technology Patents**

Oxford, UK - 28 October 2015: Oxford BioMedica plc ("Oxford BioMedica" or "the Group") (LSE: OXB), a leading gene and cell therapy group, announces that GlaxoSmithKline PLC (GSK) has exercised an option to obtain a non-exclusive licence for two rare orphan disease indications under Oxford BioMedica's LentiVector® platform technology patents. This follows an agreement signed between GSK and the Group in December 2013.

<http://otp.investis.com/clients/uk/GlaxoSmithKline2/rns/regulatory-story.aspx?cid=410&newsid=586833>

[\(Oxford BioMedica plc press release 28 October 2015\)](#)

#### **GSK's Advair® Diskus® achieves primary endpoint in LABA safety study of patients with asthma**

GlaxoSmithKline plc (GSK) today announced results from the 'LABA' (long acting beta2-agonist) safety study, AUSTRI (SAS115359). The study compared Advair® Diskus®, a combination of the LABA, salmeterol, and the inhaled corticosteroid (ICS), fluticasone propionate (FP), to FP monotherapy and showed that Advair (FSC) had a safety profile comparable to FP when used to treat adolescent and adult patients with asthma, assessed by the composite endpoint of serious asthma-related events (deaths, intubations or hospitalisations). [\(LSE announcement 27 October 2015\)](#)

#### **GSK's candidate shingles vaccine demonstrates 90% efficacy against shingles in people 70 years of age and over**

- Candidate vaccine also demonstrates efficacy of 89% against postherpetic neuralgia (PHN), a painful complication of shingles
- File submission is anticipated second half of 2016

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that the second pivotal phase III study of its candidate vaccine Shingrix™ in adults aged 70 years and over (known as ZOE-70) successfully met its

primary objective, demonstrating 90% (95% confidence interval: 84–94) efficacy against shingles compared to placebo. The high efficacy seen in ZOE-70 is in line with the efficacy shown in the first pivotal phase III study in adults aged 50 years and over (ZOE-50) presented earlier this year.

In addition, a pre-specified pooled analysis of ZOE-70 and ZOE-50 data demonstrated that the candidate vaccine effectively prevents subsequent chronic neuropathic pain, also known as postherpetic neuralgia (PHN) which is the most common severe complication of shingles. Shingrix was demonstrated to be 89% (95% confidence interval: 69– 97) efficacious in preventing PHN in people aged 70 years and over and 91% (95% confidence interval: 76– 98) efficacious in people aged 50 years and over. ([LSE announcement 27 October 2015](#))

#### **GSK provides update on LATITUDE-TIMI 60 (losmapimod cardiovascular study)**

GSK today announced that, as per the stepwise trial design of its losmapimod phase III study, LATITUDE-TIMI 60, an interim review of data from part A of the study (an initial cohort of 3,503 patients) did not indicate efficacy against the primary endpoint and did not support investment in the larger part B of the study as currently designed. ([Press release 27 October 2015](#))

#### **GSK announces positive new data comparing Incruse® Ellipta® to tiotropium and glycopyrronium in patients with COPD**

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced positive results from two head-to-head studies directly comparing the efficacy and safety of Incruse® Ellipta® (umeclidinium) to two available bronchodilator treatments, tiotropium (study 201316) or glycopyrronium (study 201315), when used by patients with COPD. ([LSE announcement 20 October 2015](#))

#### **Other newsflow during the quarter and to date**

##### **GSK appoints Dr Jesse Goodman to the Board as a Non-Executive Director**

The Company announces that Dr Jesse Goodman has been appointed to the Board of the Company as a Non-Executive Director and Scientific and Medical Expert with effect from 1 January 2016. Commenting on the appointment, Philip Hampton, Chairman, said “I am delighted that Jesse is joining the Board.

Jesse is a leader in public health who brings a wealth of expertise spanning science, medicine, vaccines, regulation and public health, and has a proven record in addressing pressing public health needs from both the academic and federal sectors, which will be invaluable to GSK. My colleagues and I very much look forward to welcoming him to the Board.”

Dr Goodman, currently Professor of Medicine at Georgetown University, previously served in senior leadership positions at the US Food and Drug Administration (‘FDA’), including most recently as FDA’s chief scientist and previously as Director of the Center for Biologics Evaluation and Research (CBER). Dr Goodman currently directs the Georgetown University Center on Medical Product Access, Safety and Stewardship (COMPASS) and is an active clinician who serves as Attending Physician in Infectious Diseases.

He received his degree in Biology from Harvard College, his doctorate from the Albert Einstein College of Medicine and his masters in public health from the University of Minnesota. Dr Goodman





is Board Certified in Internal Medicine, Infectious Diseases and Oncology and has been elected to the American Society for Clinical Investigation and to the Institute (National Academy) of Medicine.

[\(LSE announcement 23 December 2015\)](#)

In order to illustrate underlying performance, it is the Group's practice to discuss its results in terms of constant exchange rate (CER) growth. This represents growth calculated as if the exchange rates used to determine the results of overseas companies in Sterling had remained unchanged from those used in the comparative period. All commentaries are presented in terms of CER growth, unless otherwise stated.

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